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**Filed** : October 9, 2003

### **REMARKS**

The foregoing amendments and the following remarks are responsive to the February 23, 2006 Final Office Action. Claims 1, 26, 30, 37, 39, 44, 50, and 51 are amended, Claims 2-21, 23-25, 28, 29, 38, 40, 41, 45, 46, and 54-66 remain as originally filed, Claims 22, 27, 31-36, 42, 43, and 47-49 are cancelled without prejudice, and Claims 52 and 53 remain as previously presented. Thus, Claims 1-21, 23-26, 28-30, 37-41, 44-46, and 50-66 are presented for further consideration.

#### **Response to Rejection of Claims 1-21 and 23-25 Under 35 U.S.C. § 101**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 1-23 and 23-25 under 35 U.S.C. § 101 because the “claimed invention is directed to non-statutory subject matter” due to the positive recitation of “the scalp.”

Applicants respectfully submit that “the scalp” is not a component of the therapy apparatus as claimed in any of Claims 1-21 and 23-25. For example, the term “the scalp” is merely used in Claim 1 to recite the position of the element and to recite various features of the element. However, to clarify the claimed invention, Applicants have amended Claim 1 to recite “an element adapted to be interposed between the light source and the patient’s scalp.” Applicants submit that this amendment of Claim 1 clarifies that the scalp is not a component of the therapy apparatus claimed in Claims 1-21 and 23-25. Applicants respectfully request the Examiner to withdraw the rejection of Claims 1-21 and 23-25 and to pass these claims to allowance.

#### **Response to Rejection of Claims 47-49 Under 35 U.S.C. §112, Second Paragraph**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 47-49 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

As described herein, Applicants have cancelled Claims 47-49 without prejudice. Applicants respectfully request that the Examiner consider the patentability of the remaining pending claims.

#### **Response to Rejection of Claims 1-11, 14-17, 19, 20, 23-26, and 28-30 Under 35 U.S.C. § 102(b)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 1-6, 8-11, 14, 19, 24-26, and 28-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,150,704

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issued to Tatebayashi et al. ("Tatebayashi"). The Examiner also rejects Claims 1-10, 14-17, 19, 20, 24-26, and 28-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,282,797 issued to Chess ("Chess"). The Examiner also rejects Claims 1-6, 8-10, 14, 19, 23-26, and 28-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,537,304 issued to Oron ("Oron").

Claim 1

Applicants have amended Claim 1 to recite (emphasis added):

1. (Currently Amended) A therapy apparatus for treating a patient's brain, the therapy apparatus comprising:

a light source having an output emission area positioned to irradiate a portion of the brain with an efficacious power density and wavelength of light, **wherein the efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura;** and

an element adapted to be interposed between the light source and the patient's scalp, the element adapted to inhibit temperature increases at the scalp caused by the light, wherein the element is adapted to apply pressure to at least a portion of the scalp, thereby blanching the portion of the scalp and decreasing absorption of the light by blood in the scalp.

Support for this amendment is found in the present application as originally filed, including but not limited to, paragraph [0076].

As explained in the "Declaration of Luis De Taboada Pursuant to 37 C.F.R. § 1.132" (the "Declaration") submitted herewith, Applicants submit that Tatebayashi, Chess, or Oron do not disclose a therapy apparatus as recited by amended Claim 1. For example, neither Tatebayashi, Chess, nor Oron discloses "a light source having an output emission area positioned to irradiate a portion of the brain with an efficacious power density and wavelength of light, wherein the efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura."

Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Tatebayashi, Chess, and Oron, and Applicants respectfully request that the Examiner withdraw the rejection of Claim 1 and pass this claim to allowance.

Claims 2-11, 14-17, 19, 20, and 23-25

Each of Claims 2, 3, 14, and 23-25 depend from amended Claim 1, Claim 4 depends from Claim 3, each of Claims 5, 6, and 8 depend from Claim 4, Claim 7 depends from Claim 6, Claim 9 depends from Claim 8, each of Claims 10 and 11 depends from Claim 9, each of Claims 15 and

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19 depends from Claim 14, each of Claims 16 and 17 depends from Claim 15, and Claim 20 depends from Claim 19. Therefore, each of Claims 2-11, 14-17, 19, 20, and 23-25 includes all the limitations of amended Claim 1 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 1, Applicants submit that Claims 2-11, 14-17, 19, 20, and 23-25 are patentably distinguished over Tatebayashi, Chess, and Oron, and Applicants respectfully request that the Examiner withdraw the rejection of Claims 2-11, 14-17, 19, 20, and 23-25 and pass these claims to allowance.

Claim 26

Applicants have amended Claim 26 to recite (emphasis added):

26. A therapy apparatus for treating brain tissue, the therapy apparatus comprising:

a light source positioned to irradiate at least a portion of a patient's head with light having a wavelength and power density which penetrates the cranium to deliver an efficacious amount of light to brain tissue, **wherein the light has a power density between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura; and**

a material which inhibits temperature increases of the head, the material adapted to contact the head and to apply pressure to at least the irradiated portion of the patient's head, thereby blanching the irradiated portion.

For reasons similar to those stated above with regard to amended Claim 1, Applicants submit that amended Claim 26 is patentably distinguished over Tatebayashi, Chess, and Oron. Applicants respectfully request that the Examiner withdraw the rejection of Claim 26 and pass this claim to allowance.

Claims 28 and 29

Claim 28 depends from amended Claim 26, and Claim 29 depends from Claim 28. Therefore, each of Claims 28 and 29 includes all the limitations of amended Claim 26 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 26, Applicants submit that Claims 28 and 29 are patentably distinguished over Tatebayashi, Chess, and Oron, and Applicants respectfully request that the Examiner withdraw the rejection of Claims 28 and 29 and pass these claims to allowance.

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Claim 30

Applicants have amended Claim 30 to recite (emphasis added):

30. A therapy apparatus for treating a patient's brain, the therapy apparatus comprising:

a light source adapted to irradiate at least a portion of the brain with an efficacious power density and wavelength of light, **wherein the efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura;** and

an element adapted to inhibit temperature increases at the scalp, wherein the element is adapted to apply pressure to at least a portion of the scalp to blanch the portion of the scalp, wherein at least a portion of the element is in an optical path of the light from the light source to the scalp.

For reasons similar to those stated above with regard to amended Claim 1, Applicants submit that amended Claim 30 is patentably distinguished over Tatebayashi, Chess, and Oron. Applicants respectfully request that the Examiner withdraw the rejection of Claim 30 and pass this claim to allowance.

**Response to Rejection of Claims 37, 38, 44-46, 51-54, and 57-59 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 37, 38, 44-46, 51-54, and 57-59 under 35 U.S.C. § 103(a) as being unpatentable over Oron in view of U.S. Patent No. 6,312,451 issued to Streeter ("Streeter").

Claims 37 and 38

Applicants have amended Claim 37 to recite (emphasis added):

37. A method of treating brain tissue, the method comprising introducing light of an efficacious power density onto brain tissue by directing light through a blanched portion of the scalp of a patient, said directing comprising providing a sufficiently large spot size on said scalp to reduce the power density at the scalp below the damage threshold of scalp tissue, while producing sufficient optical power at said scalp to achieve said efficacious power density at said brain tissue, **wherein said efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura.**

Applicants submit that amended Claim 37 includes limitations that are not disclosed or suggested by either Oron or Streeter. For example, neither Oron nor Streeter discloses or suggests a method of treating brain tissue that comprises "introducing light of an efficacious power density onto brain tissue ... wherein said efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura." Therefore,

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Applicants submit that the combination of Oron and Streeter does not disclose or suggest all the limitations of amended Claim 37, so amended Claim 37 is patentably distinguished over Oron in view of Streeter.

Applicants further submit that the parameters recited by amended Claim 37 are not obvious in view of the prior art. As explained in the "Declaration of Luis De Taboada Under 37 C.F.R. § 1.132" ("the Declaration"), submitted herewith, a power density "between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura" achieves substantial advantages relative to the prior art.

In particular, the Declaration indicates that irradiation of a portion of the brain 2 centimeters below the dura with a power density between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> results in substantial advantages such as improved outcomes as measured with various medical outcome scales. These substantial advantages were unexpected in view of the prior art and attest to the non-obviousness of the claimed parameters. Therefore, Applicants submit that Claim 37 is patentably distinguished over the combination of Oron and Streeter.

Claim 38 depends from amended Claim 37, so Claim 38 includes all the limitations of amended Claim 37 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 37, Applicants submit that Claim 38 is patentably distinguished over the combination of Oron and Streeter.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 37 and 38 and pass these claims to allowance.

#### Claims 44-46

Applicants have amended Claim 44 to recite (emphasis added):

44. A method for treating a patient's brain, the method comprising introducing light of an efficacious power density onto **a target area of the brain at a depth of at least approximately 2 centimeters below the patient's dura** by directing light through a blanched portion of the scalp of the patient, wherein the light has a plurality of wavelengths, **and the efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at the target area.**

For reasons similar to those stated above with regard to amended Claim 37, Applicants submit that amended Claim 44 includes limitations that are not disclosed or suggested by Oron in view of Streeter and that the parameters recited by amended Claim 44 are not obvious in view of the prior art, so amended Claim 44 is patentably distinguished over Oron in view of Streeter.

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Each of Claims 45 and 46 depends from amended Claim 44, so each of Claims 45 and 46 includes all the limitations of amended Claim 44 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 44, Applicants submit that each of Claims 45 and 46 is patentably distinguished over Oron in view of Streeter.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 44-46 and pass these claims to allowance.

Claims 51-54 and 57-59

Applicants have amended Claim 51 to recite (emphasis added):

51. A method of providing a neuroprotective effect in a patient having an ischemic event in the brain, the method comprising:
- identifying a patient who has experienced an ischemic event in the brain;
  - estimating the time of the ischemic event; and
  - after estimating the time of the ischemic event, waiting to commence-administration of a neuroprotective effective amount of light energy to the brain such that the administration of light does not commence until after about two hours following the estimated time of the ischemic event, **wherein the light energy has a power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura.**

For reasons similar to those stated above with regard to amended Claim 37, Applicants submit that amended Claim 51 includes limitations that are not disclosed or suggested by Oron in view of Streeter and that the parameters recited by amended Claim 51 are not obvious in view of the prior art, so amended Claim 51 is patentably distinguished over Oron in view of Streeter.

Each of Claims 52-54 and 57-59 depends from amended Claim 51, so each of Claims 52-54 and 57-59 includes all the limitations of amended Claim 51 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 51, Applicants submit that each of Claims 52-54 and 57-59 is patentably distinguished over Oron in view of Streeter.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 51-54 and 57-59 and pass these claims to allowance.

**Response to Rejection of Claims 11-13 and 21 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 11-13 and 21 under 35 U.S.C. §103(a) as being unpatentable over Chess in view of U.S. Patent No. 5,474,528 issued to Meserol ("Meserol") and U.S. Patent No. 5,622,168 issued to Keusch et al. ("Keusch").

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Applicants submit that Chess does not disclose or suggest all the limitations of amended Claim 1, and that neither Meserol nor Keusch discloses or suggests the limitations of amended Claim 1 that are missing from Chess. Furthermore, Applicants submit that the parameters recited by amended Claim 1 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess in view of Meserol and Keusch.

Claim 3 depends from amended Claim 1, Claim 4 depends from Claim 3, Claim 8 depends from Claim 4, Claim 9 depends from Claim 8, Claim 11 depends from Claim 9, and each of Claims 12 and 13 depends from Claim 11. Therefore, each of Claims 11-13 includes all the limitations of amended Claim 1 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 1, Applicants submit that each of Claims 11-13 is patentably distinguished over Chess in view of Meserol and Keusch.

Claim 14 depends from amended Claim 1, Claim 19 depends from Claim 14, and Claim 21 depends from Claim 19. Therefore, Claim 21 includes all the limitations of amended Claim 1 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 1, Applicants submit that Claim 21 is patentably distinguished over Chess in view of Meserol and Keusch.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 11-13 and 21 and pass these claims to allowance.

#### **Response to Rejection of Claim 18 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claim 18 under 35 U.S.C. §103(a) as being unpatentable over Chess.

Applicants submit that Chess does not disclose or suggest all the limitations of amended Claim 1, and that the limitations of amended Claim 1 that are missing from Chess are not obvious. Furthermore, Applicants submit that the parameters recited by amended Claim 1 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess.

Claim 14 depends from amended Claim 1, Claim 15 depends from Claim 14, and Claim 18 depends from Claim 15. Therefore, Claim 18 includes all the limitations of amended Claim 1 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 1, Applicants submit that Claim 18 is patentably distinguished over Chess.

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Applicants respectfully request that the Examiner withdraw the rejection of Claim 18 and pass this claim to allowance.

**Response to Rejection of Claim 21 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claim 21 under 35 U.S.C. §103(a) as being unpatentable over Chess in view of U.S. Patent No. 5,643,334 issued to Eckhouse et al. ("Eckhouse").

Applicants submit that Chess does not disclose or suggest all the limitations of amended Claim 1, and that Eckhouse does not disclose or suggest the limitations of amended Claim 1 that are missing from Chess. Furthermore, Applicants submit that the parameters recited by amended Claim 1 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 1 is patentably distinguished over Chess in view of Eckhouse.

Claim 14 depends from amended Claim 1, Claim 19 depends from Claim 14, and Claim 21 depends from Claim 19. Therefore, Claim 21 includes all the limitations of amended Claim 1 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 1, Applicants submit that Claim 21 is patentably distinguished over Chess in view of Eckhouse.

Applicants respectfully request that the Examiner withdraw the rejection of Claim 21 and pass this claim to allowance.

**Response to Rejection of Claims 39-41 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 39-41 under 35 U.S.C. §103(a) as being unpatentable over Oron in view of U.S. Patent No. 6,045,575 issued to Rosen et al. ("Rosen") in view of Meserol.

Applicants have amended Claim 39 to recite (emphasis added):

39. A method of treating a patient's brain by irradiating the brain with light transmitted through the patient's scalp, the method comprising covering at least a significant portion of the patient's scalp with a light-emitting blanket, the light-emitting blanket comprising a first side in proximity to the scalp and a second side having a reflective coating to reflect light emitted away from the scalp back towards the scalp, **wherein the light has a power density between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> at a depth of approximately 2 centimeters below the patient's dura.**

Applicants submit that Oron does not disclose or suggest all the limitations of amended Claim 39, and that neither Rosen nor Meserol discloses or suggests the limitations of amended



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Claim 39 that are missing from Oron. Furthermore, Applicants submit that the parameters recited by amended Claim 39 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 39 is patentably distinguished over Oron in view of Rosen and Meserol.

Each of Claims 40 and 41 depends from amended Claim 39. Therefore, each of Claims 40 and 41 includes all the limitations of amended Claim 39 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 39, Applicants submit that each of Claims 40 and 41 is patentably distinguished over Oron in view of Rosen and Meserol.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 39-41 and pass these claims to allowance.

**Response to Rejection of Claims 55, 56, and 60-66 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claims 55, 56, and 60-66 under 35 U.S.C. §103(a) as being unpatentable over Oron in view of U.S. Patent No. 6,277,974 issued to Lo et al. ("Lo").

For reasons similar to those stated above, Applicants submit that Oron does not disclose or suggest all the limitations of amended Claim 51. Applicants also submit that Lo does not disclose or suggest the limitations of amended Claim 51 that are missing from Oron. Furthermore, Applicants submit that the parameters recited by amended Claim 51 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 51 is patentably distinguished over Oron in view of Lo.

Each of Claims 55, 56, 60, and 61 depends from amended Claim 51, each of Claims 62-64 depends from Claim 61, and each of Claims 65 and 66 depends from Claim 64. Therefore, each of Claims 55, 56, and 60-66 includes all the limitations of amended Claim 51 as well as other limitations of particular utility. For at least the reasons stated above with regard to amended Claim 51, Applicants submit that each of Claims 55, 56, and 60-66 is patentably distinguished over Oron in view of Lo.

Applicants respectfully request that the Examiner withdraw the rejection of Claims 55, 56, and 60-66 and pass these claims to allowance.

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**Response to Rejection of Claim 50 Under 35 U.S.C. § 103(a)**

In the February 23, 2006 Final Office Action, the Examiner rejects Claim 50 under 35 U.S.C. §103(a) as being unpatentable over Oron in view of Streeter and U.S. Patent No. 6,551,308 issued to Mueller et al. ("Mueller").

Applicants have amended Claim 50 to recite (emphasis added):

50. A method for treating a patient's brain, the method comprising directing an efficacious power density of light through a blanched portion of the scalp of the patient to a target area of the brain concurrently with applying an efficacious amount of ultrasonic energy to the brain, **wherein the efficacious power density is between about 0.01 mW/cm<sup>2</sup> and about 100 mW/cm<sup>2</sup> and the target area is at a depth of at least approximately 2 centimeters below the patient's dura.**

Applicants submit that Oron does not disclose or suggest all the limitations of amended Claim 50, and that neither Streeter nor Mueller discloses or suggests the limitations of amended Claim 50 that are missing from Oron. Furthermore, Applicants submit that the parameters recited by amended Claim 50 are not obvious in view of the prior art. Therefore, Applicants submit that amended Claim 50 is patentably distinguished over Oron in view of Streeter and Mueller. Applicants respectfully request that the Examiner withdraw the rejection of Claim 50 and pass this claim to allowance.

**Summary**

For the foregoing reasons, Applicants submit that Claims 1-21, 23-26, 28-30, 37-41, 44-46, and 50-66 are in condition for allowance, and Applicants respectfully request such action.

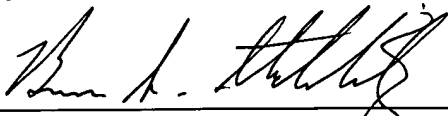
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

Dated: \_\_\_\_\_

8/21/06

By: \_\_\_\_\_

  
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